



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Egan et al.

SERIAL NUMBER : 09/905,188

EXAMINER : Cybille Delacroix-Muirheid

FILING DATE : July 13, 2001

ART UNIT : 1614

FOR : METHODS FOR TREATING FIBROTIC DISEASES OR OTHER INDICATIONS IC

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

DECLARATION OF HOWARD B. HAIMES UNDER 37 C.F.R. §1.132

I, Howard B. Haimes, of 114 Woodland Street, Natick, MA, declare and state that:

1. I received Ph.D. degree in Biochemical Cytology from Sue Golding Graduate Division of the Albert Einstein College of Medicine, Yeshiva University, Bronx, NY and a M.S. in Biochemical Cytology from Sue Golding Graduate Division of the Albert Einstein College of Medicine, Yeshiva University, Bronx, NY and an M.S. degree in Biology from Long Island University, Brooklyn, NY and a B.S degree in Biology from Union College, Schenectady, NY .
2. I am presently employed by Alteon Inc., 6 Campus Drive, Parsippany, NJ 07054, the assignee of the above-referenced patent application. I have been employed by Alteon Inc. for 1 year.
3. I have reviewed the Office Action dated August 11, 2005. I understand that claims 15 and 16 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.
4. I disagree with the Examiner's assertion that the specification does not support a method of treating, ameliorating or preventing hypertension or systolic hypertension by administering the claimed combination as the Examiner alleges the specification only provides support for the claimed combination thereby only for the treatment of heart failure, cardiomyopathy or

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heart attack. Using references available on the filing date of the instant application, one of ordinary skill in the art would readily recognize that the essential manifestation of these disorders of which to direct treatment is isolated systolic hypertension. *See*, Kannel et al., *N. Eng. J. Med.* 287: 781-787, 1972; Drayer et al., *Arch. Intern. Med.* 124: 160-164, 1969; Rabkin et al. *Ann. Intern. Med.* 88: 342-345, 1978; Kannel et al., *J. Am Med. Assoc.* 245: 1225-1229, 1981; Multiple Risk Factor Intervention Trial Research Group, *J. Am Med. Assoc.* 248: 146-147, 1982; Smulyan and Safar, *Ann. Intern. Med.* 132: 233-237, 2000. Thus, I submit that based on the state of the art at the time of filing and the disclosure in the specification at page 18, line 21 - page 19, line 31 and page 21, line 23 - page 22, line 11 that one of ordinary skill in the art would readily conclude that at the time the application was filed, Applicants had possession of the invention as claimed.

5. I further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.


Howard B. Haimes

Signed at Parsippany, NJ

this 29th day of September, 2005

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